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Reliability and validity of the Turkish version of the foot function index in patients with calcaneal heel spur

Topuk dikenli olan hastalarda ayak fonksiyon indeksinin Türkçe geçerlik ve güvenilirlik çalışması

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Abstract

Aim: One of the most extensively used questionnaires in studies and clinical trials is the Foot Function Index (FFI). The aim of our study was to evaluate the reliability and the validity of the FFI in Turkish patients with calcaneal heel spur.

Methods: A cross-sectional study was performed in 20014-2015 in Ankara, Turkey with 146 patients with calcaneal heel spur. Statistical analyses were performed using the SPSS software version 20. Intra-class correlation coefficients (ICC) and Cronbach alpha coefficients were used to determine test-retest reliability and internal consistency of FFI. Construct validity was tested by Pearson correlation coefficient approach comparing the correlation of the Visual Analogue Pain Scale (VAS-pain), foot and ankle outcome score (FAOS) and The Short Form-36 (SF-36) questionnaire with FFI.

Results: A hundred and forty six patients (125 women, 21 men) were enrolled in the study. The mean age of the patients were 46,4±10,3 years. The random ICC for the total FFI and three subscales ranged from 0.74 to 0.99. The Cronbach's alpha coefficient ranged from 0.78 to 0.83. In terms of validity, there was a significant correlation between the Turkish version of FFI, VAS, some of the sub-scales of FAOS and SF-36 scores (p<0.05).

Conclusion: The Turkish version of FFI was valid and reliable to assess the foot disease in patients with heel spur. It can be used for both in clinic and research studies in the assessment of pain, disability and limitation of the function of the foot.

Keywords: Foot function index, Reliability and validity, Foot diseases

Öz

Amaç: Ayak Fonksiyon İndeksi (Foot Function Index: FFI) klinik uygulamalar ve araştırmalarda yaygın kullanılan ölçeklerden biridir. Bu araştırmanın amacı FFI'in, topuk dikenli tanısı olan hastalarda Türkçe geçerlik ve güvenilirliğini çalışmaktır.

Yöntemler: Verilerin İstatistiksel analizleri SPSS 20 paket programı kullanılarak analiz edilmiştir. Test-tekrar test güvenilirliğini ve FFI iç tutarlılığını belirlemek için sınıf içi korelasyon katsayıları (ICC) ve Cronbach alfa katsayıları kullanılmıştır. Yapı geçerliği, vizüel analog skalası (VAS- ağrı), ayak ve ayak bileği sonuç skoru (FAOS) ve Kısa Form-36 (SF-36) ile FFI arasındaki ilişki Pearson korelasyon katsayısı ile test edilmiştir.

Bulgular: Çalışmamıza 125'i kadın 21'i erkek olmak üzere 146 hasta dahil edilmiştir. Hastaların yaş ortalaması 46,4± 10,3 yıl idi. Toplam FFI ve üç alt ölçek olan VAS, FAOS ve

SF-36 için rastgele ICC, 0,74 ile 0,99 arasında bulunmuştur. Cronbach'ın alfa güvenilirlik katsayısı en düşük 0,78 ve en büyük 0,83 olarak hesaplanmıştır. Geçerlik açısından ise FFI ile VAS, FAOS ve SF-36 puanlarının bazı alt ölçekleri arasında anlamlı ilişki bulunmuştur (p<0.05).

Sonuç: Bu çalışmada, topuk dikenli tanısı olan hastaları değerlendirmek için kullandığımız FFI'nin Türkçe versiyonunun geçerli ve güvenilir olduğu gösterilmiştir. Bu ölçeğin, klinik ve araştırmalarda ayak ağrıları, yetersizlik ve ayak fonksiyonlarını değerlendirmek için hastalara uygulanabileceğini düşünmekteyiz.

Anahtar kelimeler: Ayak fonksiyon indeksi, Geçerlik ve güvenilirlik, Ayak hastalıkları

Introduction

Foot pain has been shown to have a damaging impact on health-related quality of life across a spectrum of age groups [1]. Heel spur, is the most frequent reason of the calcaneal pain and is a common problem among adults [2]. Although the etiological mechanism of heel spur is not clearly known, it was suggested that repetitive traction of the insertion of the plantar fascia into the calcaneus and repetitive compression causes heel spurs [3].

Self-reported outcome scales have been used by clinicians and investigators to evaluate the effect of treatments directed at patients with foot problems and following impairments [4]. The use of valid, reliable, and responsive outcomes measures is important for successful clinical outcomes research. The American Orthopedic Foot and Ankle Society (AOFAS) scale is the most widely used one, in published studies to evaluate the outcomes of foot and ankle surgery [5]. Comparisons are difficult to make with these studies as a range of different measurement approaches have been used. One of the most extensively used questionnaires in studies and clinical trials is the Foot Function Index (FFI) [6-9]. This questionnaire has been developed and validated in 1991, and it has been compared and validated with other foot health questionnaires [10-14]. Previously, the adaptation of the FFI to Turkish in patients with plantar fasciitis was performed but the validity and reliability of FFI was not studied in patients with calcaneal heel spur [15]. The purpose of this study is to evaluate the reliability and validity of FFI in Turkish patients with foot pain related with calcaneal heel spur.

Materials and methods

The cross-sectional study was conducted in 20014-2015 in Ankara, Turkey. All patients gave their written informed consent to participate in this trial before enrolment and the study was approved by Ethics Committee at Ankara Training and Research Hospital. Permission to validate in Turkish the original version of the FFI was asked to the developer.

The included patients were adults >18 years old, duration of symptoms over 3 months, heel spur was diagnosed with localized tenderness at the tuberosity of calcaneus with typical radiological appearance. Patients were excluded in case of age less than 18 years, inflammatory or septic arthritis, and amputation of a limb, cancer, cognitive disorders, foot surgery and pregnancy. Also the patients with pain in the dorsiflexion of toes and patients with tenderness on the plantar fascia area indicating plantar fasciitis were excluded. The demographic properties including age, gender, occupation and body mass index (BMI) were recorded.

FFI was translated into Turkish by two Turkish physiatrists and an interpreter. After that they met in order to review the translations and inconsistencies in the translations were resolved by discussions among the translators. Independent back translation was performed by two native English speakers fluent in Turkish and with medical background. A second consensus meeting of all involved translators was held in order to check for any problems, and to establish the pre-final Turkish version of the FFI. During the translation stage of questionnaire, only one cultural adaptation was necessary regarding distance

evaluation represented in the English version by "four blocks". We have chosed to use numeric scale of distance to improve the understanding of patients. We have changed "four blocks" to 200 meters in Turkish form.

The final Turkish version was obtained after testing it on twenty patients with foot pain to determine the ease of understanding the questions. The feed-back from the pretest study group did not identify any concerns. The Turkish version of FFI was answered by the patients themselves. One physiatrist was in the interview room in order to help the patients in case they needed assistance, which was the case only in a few patients with difficulty in reading. The scale was completed by each patient twice with 10 days interval.

The FFI is a self-questionnaire made of 23 items and it is divided into three subscales: pain, disability and activity limitations for assessing patients with foot diseases [10,16]. Each item is rated on a 0-10 numeric scale and the scores of all items are summed separately for three subscales, divided by the maximum score achievable of all rated items, and finally multiplied by 100. Although all the various published translations of the FFI [17-18], included 18 items we have used the original questionnaire with 23 items.

We have used the foot and ankle outcome score (FAOS), the Short Form-36 (SF-36) questionnaire and visual analogue scale (VAS) to compare the FFI for reliability in Turkish patients with calcaneal heel spur.

The foot pain was assessed by the VAS that consisted of 0-10 cm line; 0 equal to "no pain" and 10 equal to "worst possible pain" [19].

The FAOS has been validated for use in Turkey and consists of 42 items assessing five separate patient-relevant dimensions: Pain (nine items); other symptoms like stiffness, swelling, and range of motion (seven items); activities of daily living (ADL) (17 items); sport and recreational activities (Sport/Rec) (five items; and lower limb-related quality of life (QoL) (four items). To answer each question, five Likert boxes were used (no, mild, moderate, severe, extreme) and all items was scored from zero to four. Each of the five subscale scores were calculated as the sum of the items included. Raw scores were then transformed to a scale from zero to 100. The higher total value indicates the lesser problems and/or functional limitations [20].

SF-36 has been validated for use in Turkey²¹. This questionnaire provides eight separate subscales: physical functioning (PF), role physical (RP), bodily pain (BP), general health (GH), vitality (EV), social functioning (SF), role emotional (RM), mental health (MH) which are then aggregated into two main scores: the physical composite score (PCS) and the mental composite score (MCS). The higher the score, the better was the perceived health level [21].

Statistical analyses

Data were analyzed using SPSS 20 (IBM SPSS Incorporated, Chicago, IL, USA). Descriptive analyses were applied to calculate means and standard deviations of the demographic variables. No factor analysis was performed because the factors were determined in the study of Budiman-Mak [10].

Reliability

For test-retest reliability, all patients completed the questionnaires at the same time of day, during a non-treatment period [22]. Intra-class correlation coefficients (ICC) were used to determine test-retest reliability of the scores on three subscales of FFI and total FFI. Cronbach alpha coefficients were used to determine internal consistency of the entire questionnaire and of each domain [23]. As recommended, internal consistency of a magnitude of 0.70 or greater was sought. Cronbach alpha was determined as high correlation if values in range of 0.80-0.95 were obtained, where a value >0.95 indicated excessive internal consistency. The correlation coefficient values of <0.4 show weak correlation, 0.4–0.74 illustrate moderate correlation, 0.75–0.9 indicate strong correlation, and >0.9 very strong correlation [24].

Validity

Construct validity was tested by Pearson correlation coefficient approach comparing the correlation of the similar scales of the FFI. Pearson correlation coefficient was used to evaluate the relationship between FFI and foot and ankle outcome score (FAOS), SF-36 questionnaire and Visual Analogue Pain Scale (VAS-pain). It was expected that conceptually related scales would correlate better with the FFI. The correlation coefficients are interpreted as follows: <0.4 was weak, 0.4-0.74 was moderate, 0.75 to 0.9 was strong, and >0.9 was very strong [24]. The level of significance was set at p<0.05.

Results

A hundred and ninety patients with foot pain were evaluated and 146 patients (125 women, 21 men) with heel spur were recruited for the study. The flow chart of the study is shown in figure 1. The mean age and BMI of the patients were 46.4±10.3 years and 30.7±5.4 kg/m² respectively. They had professions as follows; 67.8%, 11.6%, 15.8%, 2.1% and 2.7% of patients were housewife, officer, workman, student and retired respectively. The mean duration of the disease was 15.8±27.2 months. During the translation stage of questionnaire we have changed “four blocks” to distance of 200 meters in Turkish form.

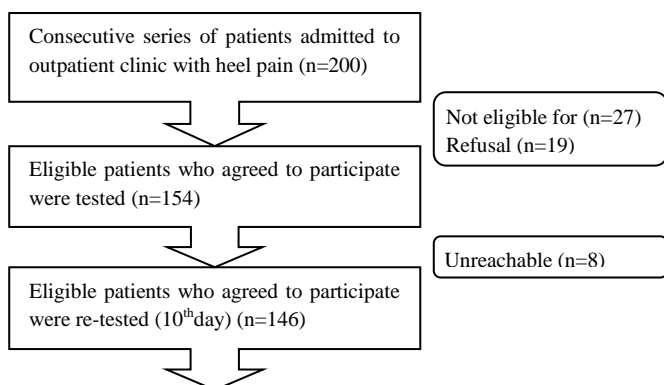


Figure 1: The flow chart of the study

Reliability

Evaluation of test-retest measurement within 10 day showed that there was no difference between two measurements as all p values were greater than 0.05. The random ICC for the total FFI and three subscales ranged from 0.74 to 0.99. The test-retest reliability of the disability with 0.97, activity with 0.99 and total FFI with 0.93 were strong, that of pain with 0.74 was

moderate. The Cronbach’s alpha coefficient ranged from 0.78 to 0.83 (Table 1).

Table 1: Descriptive statistics and reliability of FFI (n=146)

	Mean Score±SD		p	ICC (95% CI)	Cronbach’s alpha
	First assessment	Second assessment			
Pain	71.1±9.7	73.7±12.3	0.057	0.74 (0.68-0.80)	0.81
Disability	74.5±11.4	76.4±11.6	0.158	0.97 (0.94-0.99)	0.83
Activity	26.4±14.1	26.7±14.3	0.856	0.99 (0.97-1.00)	0.81
TFFI	57.3±8.6	58.9±8.8	0.758	0.93 (0.88-0.97)	0.78

SD: Standard deviation, ICC: Intra class correlation coefficient, CI: Confidence interval

Validity

In terms of validity, there was a significant correlation between the Turkish version of FFI, VAS, some of the sub-scales of FAOS and SF-36 scores (p<0.05). Table 2 gives an overview of correlation coefficients between total and subscales of FFI and the VAS, FAOS and SF-36.

Table 2: Correlation between VAS, the FFI subscales, FAOS and SF-36 subscales (construct validity)

	Pain	Disability	Activity	TFFI
VAS	0.553**	0.441**	0.284**	0.557**
p-Value	0.000	0.000	0.001	0.000
FAOS- Pain	-0.151	-0.212*	-0.098	-0.204*
p-Value	0.069	0.010	0.238	0.014
FAOS-Symptoms	-0.044	-0.028	0.090	-0.078
p-Value	0.597	0.737	0.280	0.307
FAOS-ADL	-0.227**	-0.198*	-0.055	-0.143
p-Value	0.006	0.017	0.511	0.737
FAOS-Sport/rec	-0.095	-0.243**	0.115	-0.205*
p-Value	0.256	0.003	0.169	0.028
FAOS-QoL	-0.160	-0.139	-0.041	-0.144
p-Value	0.054	0.094	0.622	0.066
SF36-Physical functioning	-0.191*	-0.161	-0.149	-0.224**
p-Value	0.021	0.052	0.07	0.002
SF36-Role physical	-0.085	-0.174*	0.044	-0.085
p-Value	0.309	0.035	0.597	0.309
SF36-Bodily pain	-0.356**	-0.232**	0.039	-0.257**
p-Value	0.000	0.005	0.642	0.000
SF36-General health	-0.100	-0.16	-0.018	-0.055
p-Value	0.230	0.849	0.825	0.523
SF36-Vitality	-0.204*	-0.119	-0.028	-0.145
p-Value	0.013	0.152	0.737	0.149
SF36-Social functioning	-0.145	-0.110	-0.100	-0.157
p-Value	0.082	0.187	0.581	0.747
SF36-Role emotional	-0.131	-0.171*	0.046	-0.100
p-Value	0.116	0.039	0.581	0.747
SF36-Mental health	-0.179*	-0.152	0.006	-0.131
p-Value	0.030	0.067	0.939	0.339

TFFI: total function test, *p<0.05, **p<0.01

Discussion

One in every five middle-aged person presents foot and ankle pain, and this may compromise locomotion, impairment of balance and a limitation in functional activities of daily living. Pathological conditions of the ankle and foot are under evaluation by healthcare professionals and researchers, using self-reported outcome instruments. These instruments make it possible to use of reliable measurements for patients’ perceptions, and specific instruments have been standardized in order to follow up and evaluate the effects of a given intervention [7,9].

The FFI has been widely used in studies of foot and ankle problems, related with various pathologies like acute and chronic diseases, congenital problems, injuries and surgical corrections [11]. FFI is a self- questionnaire with a short administration time making it easy to use in daily practice. It is easy to fill out. The reliability and validity of FFI was evaluated by many studies in different cultural populations [17,25,26]. Beside this it was classified as the fourth most used questionnaire for ankle and foot evaluations between 2002–2011 years [9]. Calcaneal heel spur is a common disorder of the foot that occurs in 15–20 % of the population and it can be seen in every age.

The symptoms of calcaneal spur is more frequently seen in overweight, elderly, and female patients [27,28]. Although calcaneal heel spur can be associated with plantar fasciitis the differential diagnosis can be made by simple clinical tests and physical examination findings.

Herein we aimed to evaluate the validation and reliability the FFI questionnaire in Turkish patients with foot pain due to calcaneal heel spurs. Reliability and validity study of foot function index was first performed by Budiman-Mak et al. [10] in patients with rheumatoid arthritis. For the analysis of our study, the total FFI score was used as well as subscales because we suggest that it is more practical in clinical application similar to a previous study and unlike previous studies that used the scores of each subscale [16,17,25,26,29].

In our study, there was a high correlation between all items of the Turkish FFI questionnaire, which demonstrates good internal consistency. We found that all subscales of the Turkish FFI had good internally consistency and test-re-test reliability similar to Budiman-Mak et al [10]. The Turkish version was reliable for the total questionnaire and subscales domains (Cronbach alpha: 0.78). Furthermore, the reliability studies of the subscales "pain", "disability" and "activity limitation" showed moderate to strong reproducibility with ICC of 0.74, 0.97, 0.99 respectively similar to Martinez et al who tested the validity of Brazilian-Portuguese FFI [9]. These results were higher than the recommended level of 0.70.

The Turkish version of FFI was reliable and internally consistent for the total FFI score, pain, disability, activity limitation subscales of FFI (Cronbach alpha: 0.78, 0.81, 0.83, 0.81 respectively) and it was comparable to those observed in the original version and in other validation studies [10,17,30]. It is known that, a too high Cronbach's alpha coefficient value might indicate a high level of item redundancy. For this reason, it is suggested that Cronbach's alpha should be above 0.70 but not higher than 0.90 similar to the results of our study [21]. Besides, these findings show that the items of the Turkish version are homogenous, as the original version [9,10].

We have used VAS-pain, FAOS and SF-36 for validity analysis. We found positive correlations between VAS-pain and total and subscores of FFI but inverse correlation was observed between subscale of FAOS and SF-36. The scoring system in FFI indicates that the lower are the scores, the healthier are the patients, while in the latter two questionnaires the inverse is the case.

The total score and subscores of Turkish FFI correlated moderately with VAS (weakly with the activity subscales of FFI) similar to Spanish adaptation of FFI [29], while German and Italian adaptation of FFI found a strong correlation with VAS [16,17]. We found weak correlation with FAOS-pain, FAOS-ADL, FAOS-sport and physical function, physical role, bodily pain, vitality emotional role and mental health of SF-36. The values of FAOS-symptoms and FAOS-QoL did not correlate with the total and the subscales of Turkish FFI while it was reported that all subscores of FAOS except FAOS-symptoms were correlated strongly with FFI scores in a previous study [9].

As far as we can see, we have found a correlation with all subscales of SF-36 except two subscales (general health and social functioning) unlike to other studies [9-10,16]. Social and

general health status is unrelated to orthopedic problems and could be inconsistent with findings [9]. Spanish adaptation of FFI had a weak correlation with physical and mental health of SF-36 [29]. German adaptation of FFI found a moderate with the physical SF-36, and weak with the mental SF-36 scores [17], while Chinese adaptation to had a strong correlation with the physical SF-36, but weak with the mental SF-36 scores [26]. In our study total FFI scores were correlated moderately with VAS, weakly with FAOS-pain, FAOS-sport, SF-36 physical function and bodily pain subscores. The main problem we encountered in the analysis of parameters consisted with the items of activity limitation. This may be due to the fact that most of our patients with pain and disability did not use assistive devices and had almost no activity limitations. Landorf et al. [13] suggested that FFI has limitations in people without marked disability, particularly in the activity limitation subscale and this subscale was prone to inconsistent scoring. However we considered it would be more appropriate to apply the original form and included the activity limitation subscale. Most of the previous studies excluded the activity limitation subscale of FFI in their validity studies [16,17,30].

One of the limitations of our study is to evaluate patients with only calcaneal heel spur; however, it may be necessary to assess the treatment effects indicating the responsiveness of Turkish version of FFI, which may be a subject of future studies. Also further testing in different conditions related with foot pain may be needed to ensure the validity and reliability of this scale in other Turkish patients groups with foot pain.

Conclusion

Our study has demonstrated that the FFI was easy to use, valid and reliable to assess the foot disease in Turkish patients with calcaneal heel spur. It can be used for both in clinic and research studies in the assessment of pain, disability and limitation of the function of the foot. Future studies should be encouraged to investigate the responsiveness of this questionnaire pre and after treatments of specific foot diseases. But we have observed that activity limitation correlated with VAS-pain only. Therefore the use of 'activity limitation' subscale may not be necessary in clinical assessments.

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